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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,386	08/27/2003	Maibritt Bansholm Andersen	6150.210-US	7203
7590	05/24/2004			
Reza Green, Esq. Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540			EXAMINER DESAI, RITA J	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,386

Applicant(s)

ANDERSEN ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-26-03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

The priority to US 09771770 has been acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1,3-8 in part, drawn to a method of treating anorexia, lack of appetite, obesity and type II diabetes with compounds NNC 26-1291, NNC 26-1187, , MK 0677, classified in class 514 , 546 and various subclasses.
- II. Claims 1,3-8 in part, drawn to a method of treating anorexia, lack of appetite, obesity and type II diabetes with compounds NN703, classified in class 514, 562 and various subclasses.
- III. Claims 1-8 in part , drawn to method of treating with other compounds classified in class 514 and various subclasses. A further election of a single disclosed species is required. This group is subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to treating diseases using different compounds and drugs.

These are considered different inventions. Since there are numerous drugs that can treat the same disease.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III , restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Reza on 5/14/04 a provisional election was made with traverse to prosecute the invention of Group I , claims 1-8 in part drawn to a method of treating anorexia, lack of appetite, obesity and type II diabetes with compounds NNC 26-1291, NNC 26-1187, , MK 0677, classified in class 514 , 546 and various subclasses.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-8 in part are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites “regulating food intake “ which is not clear, since either it can decrease or increase the intake. Compounds do not work in both ways , either it can decrease or increase the food intake.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et US 5723616.

See abstract which discloses MK0677 for treating conditions which require stimulation of the growth hormone.

The reference clearly states that it can be used for food production, which is related to the amount of food intake .

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Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5767,124

Draper et al .

The reference discloses the compounds useful in food animals to promote growth thereby rendering the production of edible meat products more efficient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draper et al 5767124 , Haughton et al US 5723616.

Applicant's claims are drawn to treating these various diseases such as obesity, anorexia, food intake , diabetes II., using the specific compounds .

Determination of the scope and content of the prior art (MPEP §2141.01)

The references discloses the compounds to increase the growth in the food animals.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art does not specifically teach obesity, and anorexia and diabetes.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Even though the reference does not teach the anorexia , obesity and diabetes , theses diseases all have their foundation in the regulation of food intake , thus it would be obvious for one skill in the art that substances that regulate the food intake would also be used to treat anorexia and may also have some effect in diabetes and obesity.

Conclusion

The claims are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
May 18, 2004

5/19/04